ASPIDE Médical	PREMARKET NOTIFICATION 510(k) SURGICAL MESH: SURGIMESH®XD	

510(k) Summary

SURGIMESH®XD JUN 2 5 2010

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

ASPIDE MEDICAL
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Contact Person: Mr. William Wiecek

Date Prepared: June 24, 2010

Name of Device and Name/Address of Sponsor

SURGIMESH®XD

ASPIDE MEDICAL
246 allée Lavoisier
42350 LA TALAUDIERE (FRANCE)

Common or Usual Name

Polymeric Surgical Mesh

Classification Name

Surgical Mesh

Predicate Devices

(1) ASPIDE MEDICAL's SURGIMESH WN (K061445);
(2) BARD's 3D MAX (K081010); and
(3) PROMEDON's SAFYRE SLING (K020007).

Intended Use / Indications for Use

The SURGIMESH®XD mesh is recommended for reinforcement of hernia defects. The hernia repair is for an inguinal hernia. The SURGIMESH®XD implant is indicated for use via an extraperitoneal approach either by open or laparoscopic surgery.

Technological Characteristics

The SURGIMESH®XD consists of non-absorbable synthetic mesh, made of polypropylene. The SURGIMESH®XD has a 3D shape to fit the inguinal anatomy.

In addition, two translucent windows are incorporated into the SURGIMESH®XD implant to allow proper positioning of the implant. The two windows allow the surgeon to place the implant in the correct anatomical location using the Cooper's ligament and the spermatic cord as anatomical guides in repairing a hernia defect.

SURGIMESH®XD mesh is supplied sterile.

Performance Data

Preclinical testing was conducted. Biocompatibility, product structure, and final product specifications were all tested. In all instances, the SURGIMESH®XD functioned as intended and the results observed were as expected. Specifically, the company conducted the following performance testing:

- Biocompatibility testing in accordance with ISO 10993-1 standards were conducted and results demonstrated that the device is biocompatible per these standards;
- Sterilization validation testing in accordance with ISO 10993-7, ISO 11137-1, ISO 14937, and USP 28 and results demonstrated that the device is sterile per these standards;
- Product packaging testing in accordance with ISO 11607 and results demonstrated that the device packaging has the appropriate sealing characteristics;
- The device structure and product characterization testing was performed in accordance with ISO 5084, ISO 3801, ISO 9073-3, ISO 9073-4, ISO 9073-7, ISO 13934-1 and ISO 13938-1 and results demonstrated the SURGIMESH®XD specifications are substantially similar to the identified predicate device specifications. Testing was also perform in accordance with FDA's Guidance Document entitled, *Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh* (March 2, 1999).

Substantial Equivalence

The SURGIMESH®XD is substantially equivalent to: (1) ASPIDE MEDICAL's SURGIMESH WN (K061445); (2) BARD's 3D MAX (K081010); and (3) PROMEDON's SAFYRE SLING (K020007).

The SURGIMESH®XD has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the SURGIMESH®XD and its predicate devices raise no new issues of safety or effectiveness. The SURGIMESH®XD mesh's mechanical and material characteristics are substantially equivalent to its predicate devices. Thus, the SURGIMESH®XD is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 25 2010

Aspide Medical
% Hogan & Hartson, LLP
Mr. Howard M. Holstein
Columbia Square
555 Thirteenth Street Northwest
Washington, District of Columbia 20004-1109

Re: K092233
Trade/Device Name: SURGIMESH®XD
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: June 14, 2010
Received: June 14, 2010

Dear Mr. Holstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR Peter D Pinnow MD
DEP DIR

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

Device Name: SURGIMESH®XD

Indications for Use:

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Prescription Use ___X__ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092233